

AMENDED IN ASSEMBLY MAY 3, 2001

CALIFORNIA LEGISLATURE—2001–02 REGULAR SESSION

ASSEMBLY BILL

No. 586

Introduced by Assembly Member Nation

February 21, 2001

An act to amend Section 1206.5 of, *to add Section 4052.1 to, and to repeal Section 4102 of*, the Business and Professions Code, relating to ~~clinical laboratory technology~~ *pharmacists*.

LEGISLATIVE COUNSEL'S DIGEST

AB 586, as amended, Nation. ~~Clinical laboratory technology: pharmacists~~ *Pharmacists: performance of routine patient assessments procedures and skin puncture.*

Existing law prohibits the performance of a clinical laboratory test or examination classified as waived *or of moderate complexity* under the federal Clinical Laboratory Improvement Amendments of 1988 unless it is performed under the overall operation and administration of the laboratory director, as specified, and is performed by a designated healing arts practitioner. ~~Existing law includes among these practitioners, including a pharmacist, if ordering drug therapy-related laboratory tests in compliance with provisions of existing law regulating that practice.~~ *The Pharmacy Law regulates the practice of pharmacy and authorizes a pharmacist to perform skin puncture in connection with routine patient assessment procedures, defined as including waived or moderate complexity tests, subject to the existing law provisions governing the performance of those tests by a pharmacist.*

This bill would ~~correct an erroneous cross-reference within that provision~~ delete moderate complexity tests from the definition of patient assessment procedures and would make the performance of those procedures subject to the supervision of a laboratory director.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1206.5 of the Business and Professions
- 2 Code is amended to read:
- 3 1206.5. (a) Notwithstanding subdivision (b) of Section
- 4 1206, no person shall perform a clinical laboratory test or
- 5 examination classified as waived under CLIA unless the clinical
- 6 laboratory test or examination is performed under the overall
- 7 operation and administration of the laboratory director, as
- 8 described in Section 1209, including, but not limited to,
- 9 documentation by the laboratory director of the adequacy of the
- 10 qualifications and competency of the personnel, and the test is
- 11 performed by any of the following persons:
- 12 (1) A licensed physician and surgeon holding a M.D. or D.O.
- 13 degree.
- 14 (2) A licensed podiatrist or a licensed dentist if the results of the
- 15 tests can be lawfully utilized within his or her practice.
- 16 (3) A person licensed under this chapter to engage in clinical
- 17 laboratory practice or to direct a clinical laboratory.
- 18 (4) A person authorized to perform tests pursuant to a
- 19 certificate issued under Article 5 (commencing with Section
- 20 101150) of Chapter 2 of Part 3 of Division 101 of the Health and
- 21 Safety Code.
- 22 (5) A licensed physician assistant if authorized by a supervising
- 23 physician and surgeon in accordance with Section 3502 or Section
- 24 3535.
- 25 (6) A person licensed under Chapter 6 (commencing with
- 26 Section 2700).
- 27 (7) A person licensed under Chapter 6.5 (commencing with
- 28 Section 2840).
- 29 (8) A perfusionist if authorized by and performed in
- 30 compliance with Section 2590.



(9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.

(11) A pharmacist, *as defined in Section 4036*, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of, or ~~of~~ subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052, *or if performing routine patient assessment procedures in compliance with Section 4052.1*.

(12) Other health care personnel providing direct patient care.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A perfusionist if authorized by and performed in compliance with Section 2590.

1 (8) A respiratory care practitioner if authorized by and
2 performed in compliance with Chapter 8.3 (commencing with
3 Section 3700).

4 (9) A person performing nuclear medicine technology if
5 authorized by and performed in compliance with Article 6
6 (commencing with Section 107115) of Chapter 4 of Part 1 of
7 Division 104 of the Health and Safety Code.

8 (10) Any person if performing blood gas analysis in
9 compliance with Section 1245.

10 (11) (A) A person certified as an “Emergency Medical
11 Technician II” or paramedic pursuant to Division 2.5
12 (commencing with Section 1797) of the Health and Safety Code
13 while providing prehospital medical care, a person licensed as a
14 psychiatric technician under Chapter 10 (commencing with
15 Section 4500) of Division 2, as a vocational nurse pursuant to
16 Chapter 6.5 (commencing with Section 2840) of Division 2, or as
17 a midwife licensed pursuant to Article 24 (commencing with
18 Section 2505) of Chapter 5 of Division 2, or certified by the
19 department pursuant to Division 5 (commencing with Section
20 70001) of Title 22 of the California Code of Regulations as a nurse
21 assistant or a home health aide, who provides direct patient care,
22 if the person is performing the test as an adjunct to the provision
23 of direct patient care by the person, is utilizing a point-of-care
24 laboratory testing device at a site for which a laboratory license or
25 registration has been issued, meets the minimum clinical
26 laboratory education, training, and experience requirements set
27 forth in regulations adopted by the department, and has
28 demonstrated to the satisfaction of the laboratory director that he
29 or she is competent in the operation of the point-of-care laboratory
30 testing device for each analyte to be reported.

31 (B) Prior to being authorized by the laboratory director to
32 perform laboratory tests or examinations, testing personnel
33 identified in subparagraph (A) shall participate in a preceptor
34 program until they are able to perform the clinical laboratory tests
35 or examinations authorized in this section with results that are
36 deemed accurate and skills that are deemed competent by the
37 preceptor. For the purposes of this section, a “preceptor program”
38 means an organized system that meets regulatory requirements in
39 which a preceptor provides and documents personal observation



1 and critical evaluation, including review of accuracy, reliability,
2 and validity, of laboratory testing performed.

3 (12) Any other person within a physician office laboratory if
4 the test is performed under the supervision of the patient's
5 physician and surgeon or podiatrist who shall be accessible to the
6 laboratory to provide onsite, telephone, or electronic consultation
7 as needed, and shall: (A) ensure that the person is performing test
8 methods as required for accurate and reliable tests; and (B) have
9 personal knowledge of the results of the clinical laboratory testing
10 or examination performed by that person before the test results are
11 reported from the laboratory.

12 (13) A pharmacist, if ordering drug therapy-related laboratory
13 tests in compliance with clause (ii) of subparagraph (A) of
14 paragraph (5) of, or subparagraph (B) of paragraph (4) of,
15 subdivision (a) of Section 4052.

16 (c) Notwithstanding subdivision (b) of Section 1206, no person
17 shall perform clinical laboratory tests or examinations classified
18 as of high complexity under CLIA unless the clinical laboratory
19 test or examination is performed under the overall operation and
20 administration of the laboratory director, as described in Section
21 1209, including, but not limited to, documentation by the
22 laboratory director of the adequacy of the qualifications and
23 competency of the personnel, and the test is performed by any of
24 the following persons:

25 (1) A licensed physician and surgeon holding a M.D. or D.O.
26 degree.

27 (2) A licensed podiatrist or a licensed dentist if the results of the
28 tests can be lawfully utilized within his or her practice.

29 (3) A person licensed under this chapter to engage in clinical
30 laboratory practice or to direct a clinical laboratory if the test or
31 examination is within a specialty or subspecialty authorized by the
32 person's licensure.

33 (4) A person authorized to perform tests pursuant to a
34 certificate issued under Article 5 (commencing with Section
35 101150) of Chapter 2 of Part 3 of Division 101 of the Health and
36 Safety Code if the test or examination is within a specialty or
37 subspecialty authorized by the person's certification.

38 (5) A licensed physician assistant if authorized by a supervising
39 physician and surgeon in accordance with Section 3502 or Section
40 3535.

1 (6) A perfusionist if authorized by and performed in
2 compliance with Section 2590.

3 (7) A respiratory care practitioner if authorized by and
4 performed in compliance with Chapter 8.3 (commencing with
5 Section 3700).

6 (8) A person performing nuclear medicine technology if
7 authorized by and performed in compliance with Article 6
8 (commencing with Section 107115) of Chapter 4 of Part 1 of
9 Division 104 of the Health and Safety Code.

10 (9) Any person if performing blood gas analysis in compliance
11 with Section 1245.

12 (10) Any other person within a physician office laboratory if
13 the test is performed under the onsite supervision of the patient's
14 physician and surgeon or podiatrist who shall: (A) ensure that the
15 person is performing test methods as required for accurate and
16 reliable tests; and (B) have personal knowledge of the results of
17 clinical laboratory testing or examination performed by that
18 person before the test results are reported from the laboratory.

19 (d) Clinical laboratory examinations classified as
20 provider-performed microscopy under CLIA may be personally
21 performed using a brightfield or phase/contrast microscope by one
22 of the following practitioners:

23 (1) A licensed physician and surgeon using the microscope
24 during the patient's visit on a specimen obtained from his or her
25 own patient or from a patient of a group medical practice of which
26 the physician is a member or employee.

27 (2) A nurse midwife holding a certificate as specified by
28 Section 2746.5, a licensed nurse practitioner as specified in
29 Section 2835.5, or a licensed physician assistant acting under the
30 supervision of a physician pursuant to Section 3502 using the
31 microscope during the patient's visit on a specimen obtained from
32 his or her own patient or from the patient of a clinic, group medical
33 practice, or other health care provider of which the certified nurse
34 midwife, licensed nurse practitioner, or licensed physician
35 assistant is an employee.

36 (3) A licensed dentist using the microscope during the patient's
37 visit on a specimen obtained from his or her own patient or from
38 a patient of a group dental practice of which the dentist is a member
39 or an employee.

1 SEC. 2. Section 4052.1 is added to the Business and
2 Professions Code, to read:

3 4052.1. Notwithstanding Section 2038 or any other provision
4 of law, a pharmacist may perform routine patient assessment
5 procedures and may perform skin puncture in the course of
6 performing those procedures. For purposes of this section,
7 “routine patient assessment procedures” means: (a) procedures
8 that a patient could, with or without a prescription, perform for
9 himself or herself, or (b) clinical laboratory tests that are classified
10 as waived pursuant to the federal Clinical Laboratory
11 Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the
12 regulations adopted thereunder by the federal Health Care
13 Financing Administration, as authorized by paragraph (11) of
14 subdivision (a) of Section 1206.5. A pharmacist performing these
15 functions shall, at the direction of the patient, report the results
16 obtained from a blood test to the patient and the patient’s physician
17 of choice. Any pharmacist who performs the service authorized by
18 this section shall not be in violation of Section 2052.

19 SEC. 3. Section 4102 of the Business and Professions Code is
20 repealed.

21 ~~4102.—Notwithstanding Section 2038 or any other provision of~~
22 ~~law, a pharmacist may perform skin puncture in the course of~~
23 ~~performing routine patient assessment procedures. For purposes~~
24 ~~of this section, “routine patient assessment procedures” means (a)~~
25 ~~procedures that a patient could, with or without a prescription,~~
26 ~~perform for himself or herself, and (b) clinical laboratory tests that~~
27 ~~are classified as waived or moderate pursuant to the federal~~
28 ~~Clinical Laboratory Improvement Amendments of 1988 (42~~
29 ~~U.S.C. Sec. 263a) and the regulations adopted thereunder by the~~
30 ~~federal Health Care Financing Administration, as authorized by~~
31 ~~paragraph (11) of subdivision (a) and paragraph (13) of~~
32 ~~subdivision (b) of Section 1206.5. A pharmacist performing these~~
33 ~~functions shall, at the direction of the patient, report the results~~
34 ~~obtained from a blood test to the patient and the patient’s physician~~
35 ~~of choice. Any pharmacist who performs the service authorized by~~
36 ~~this section shall not be in violation of Section 2052.~~